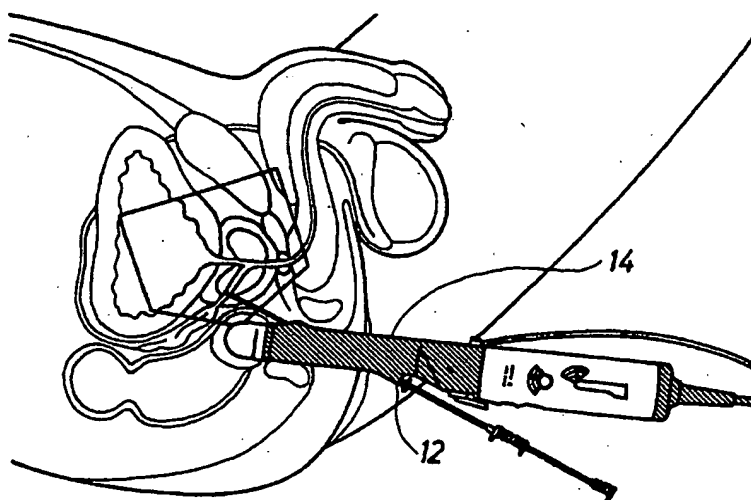


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(21) International Application Number: PCT/DK99/00001 (22) International Filing Date: 5 January 1999 (05.01.99) (30) Priority Data: 0012/98 7 January 1998 (07.01.98) DK (71) Applicant (for all designated States except US): B-K MEDICAL A/S [DK/DK]; Sandtoften 9, DK-2820 Gentofte (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): SASADY, Niels-Chr. [DK/DK]; Egehegnet 18, DK-2850 Nærum (DK). (74) Agent: CHAS. HUDE A/S; H.C. Andersens Boulevard 33, DK-1553 Copenhagen V (DK).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>With amended claims.</i>

(54) Title: ULTRASOUND PROBE WITH A DETACHABLE NEEDLE GUIDE, FOR COLLECTING TISSUE SAMPLES

**(57) Abstract**

An apparatus for insertion into the human body and which comprises one or more optionally scanning transducers (17, 18) and a needle guide (12), which can be operated from the outside. The needle guide (12) is used for collecting tissue samples from the human body. According to the invention the needle guide (12) is separated from the other part of the apparatus which for hygienic reasons is covered by a sterile sheath (14). The needle guide (12) is thus attached to the other part of the catheter via the sheath. In other words the needle guide (12) is arranged outside the sheath (14) in such a manner that the needle not penetrate the sterile sheath (14), which otherwise would entail that the apparatus should be disinfected after use.

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ULTRASOUND PROBE WITH A DETACHABLE NEEDLE GUIDE, FOR COLLECTING TISSUE SAMPLES

Technical Field

The invention relates to an apparatus for insertion into the human body and which comprises one or more optionally scanning transducers of which at least one preferably scans in the longitudinal direction, and a needle guide, which can be operated from the outside and used for collecting tissue samples from the human body.

Background Art

When inserted into a patient's anus, such an apparatus is able to locate the internal organs, such as the prostate. If a sample is to be obtained from the area adjacent the neck of the bladder, it is possible to collect the sample by inserting a needle from the outside, the needle holder being attached to the apparatus as shown in Fig. 1. However this requires that a local anaesthetic is applied to the insertion point of the needle, as the area close to the surface of the skin contains many sensory nerves. It is however desirable to avoid such a local anaesthetic. Accordingly it has been desired to insert the needle through the intestinal wall at the anus, confer Fig. 2, whereby a local anaesthetic is not required, as the internal organs are not that sensitive. At the same time it is desirable that the apparatus is covered by a sterile sheath in use such that subsequent disinfection thereof is avoided, naturally the sterile sheath must not be damaged by the needle guide.

20 Brief Description of the Invention

The object of the invention is thus to provide an apparatus with a needle guide which cannot damage a sterile sheath. At the same time the needle is to be in a plane substantially in the longitudinal direction.

An apparatus of the above type is according to the invention characterised in that the needle guide is separate from the other part of the apparatus which for hygienic reasons is covered by a sterile sheath. The needle guide is thus attached to the part of the apparatus on the outer side of the sterile sheath. In other words the needle guide is arranged outside the sheath such that the needle need not penetrate the sheath, which otherwise would entail that the apparatus should be disinfected after use.

In a particularly advantageous embodiment of the invention the needle guide is retained by being pressed into a recess in the other part of the apparatus after the sterile sheath has been placed on the apparatus. The needle guide is typically disposable and can be discarded after use.

Optionally according to the invention the needle guide may be retained by means of a needle guide holder which is clipped firmly onto the other part of the apparatus after the sterile sheath has been arranged on the apparatus.

Brief Description of the Drawings

The invention is explained in greater detail below with reference to the accompanying drawings, in which

Fig. 1 shows a known apparatus for insertion into the human body,

Fig. 2 shows an apparatus according to the invention for insertion into the human body, and

Figs. 3 and 4 show an optional embodiment of the apparatus according to the invention in assembled and separated state.

Best Mode for Carrying Out the Invention

Transrectal ultrasound scanning of the prostate is a valuable method for detection and monitoring of diseases in the prostate.

Fig. 1 shows a known apparatus 1 for insertion into a patient's anus. By means of the apparatus an ultrasound scanning of for instance the prostate can be performed. Based on the ultrasound image of the prostate, a biopsy stylet is then inserted, a special holding member 2 for the stylet being attached to the apparatus. The holding member 2 ensures that the stylet is inserted substantially parallel to the apparatus 1. The holding member 2 is provided with a plurality of holes such that the suitable distance to the apparatus can be selected. During insertion, the stylet is visible on the ultrasound image. However it may be necessary to apply a local anaesthetic before inserting the stylet.

Fig. 2 shown an apparatus according to the invention for insertion into the human body through the intestinal wall near the anus. At the end of the apparatus two ultrasonic transducers 17, 18 are provided; one ultrasonic transducer 17, which is able to scan in the longitudinal direction of the apparatus, and one ultrasonic transducer 18 which is able to scan across the longitudinal direction. As a result a fine image of the positioning of the patient's internal organs is obtained. It may be of interest to have a screen display of the precise position of the prostate.

The apparatus with the ultrasonic transducers 17, 18 is covered by a sterile sheath 14 such that the apparatus never comes into direct contact with the patient, whereby disinfection of the apparatus after use is not needed, as the apparatus is ready for reuse after a minor cleaning thereof when the sheath 14 has been removed. An inclining groove or recess is, however, provided on one side of the apparatus to receive a needle guide 12, after the sterile sheath 14 has been placed on the apparatus. Consequently, the needle guide 12 does not come into direct contact with the apparatus. The

needle guide 12 is, however, retained in relation to the apparatus inter alia due to the additional friction caused by the sheath 14, said friction possibly being provided by means of indentations or grooves. Arranging the needle guide 12 in this manner is particularly advantageous in that the needle thus never penetrates the sheath 14. As
5 a result the apparatus is not unnecessarily contaminated and thus need not be disinfected after each use.

After the apparatus with the needle guide 12 has been inserted into the anus and the internal organs in question have been located on the screen by means of the ultrasonic transducers 17,18, a biopsy needle is inserted through the needle guide 12 and the
10 penetration of the needle, until the needle tip reaches the organ, from which the sample is to be collected, is monitored on the screen. The biopsy needle is inserted through the needle guide 12 by hand.

When the desired number of samples has been collected, the needle and the entire apparatus are removed, whereafter it is sufficient to remove the needle guide 12 and
15 the sheath 14 and clean the apparatus, which then is ready to be reused.

The ultrasonic transducers 17, 18 and the pertaining displays and electronic circuits are conventional types and are thus not described in detail.

Figs. 3 and 4 shows an optional embodiment of the apparatus, in which the needle guide 12 is retained by means of a separate needle guide holder 16. The needle guide
20 holder is clipped firmly onto the other part of the catheter after the sterile sheath 14 has been arranged thereon and is formed of an oblong body of a material, which can be sterilised, such as stainless steel. The oblong body is formed as a sector of a circle in cross-section and substantially fits into a corresponding tap in the other part of the apparatus. The oblong body is provided with a projecting knot 19 mating with a
25 corresponding opening 20 in the tap. When inserted into the opening 20, the needle guide holder is retained by being clipped thereon by means of special clipping mem-

bers led partly around the apparatus. A groove 22, in which the needle guide 12 can be placed, is provided on the plane inner surface of the needle guide holder 16. The needle guide 12 is discarded after use, while the needle guide holder 16 may be disinfected by means of an autoclave.

- 5 In an optional embodiment the needle guide and the needle guide holder are formed integrally.

Claims

1. Apparatus for insertion into the human body and which comprises one or more optionally scanning ultrasonic transducers (17,18), of which at least one preferably
5 scanning in the longitudinal direction, and a needle guide (12) which can be operated from the outside and used for collecting tissue samples from the human body, the needle guide (12) being separate from the other part of the apparatus which for hygienic reasons is covered by a sterile sheath (14).
2. Apparatus according to claim 1, c h a r a c t e r i s e d in that the needle guide (12)
10 is retained by being pressed into a recess in the other part of the apparatus after the sterile sheath (14) has been arranged on the apparatus.
3. Apparatus according to claim 1, c h a r a c t e r i s e d in that the needle guide (12) is retained by means of a needle guide holder (16) which can be clipped firmly onto the other part of the apparatus after the sheath (14) has been arranged on the appa-
15 tus.
4. Apparatus according to claim 3, c h a r a c t e r i s e d in that the needle guide holder (16) is formed as a sector of circle in cross-section.
5. Apparatus according to claims 3 or 4, c h a r a c t e r i s e d in that the needle guide and the needle guide holder are formed integrally.

AMENDED CLAIMS

[received by the International Bureau on 04 June 1999 (04.06.99);
original claims 1-5 replaced by amended claims 1-4 (1 page)]

1. Apparatus for insertion into the human body and which comprises one or more optionally scanning ultrasonic transducers (17, 18), of which at least one preferably scanning in the longitudinal direction, and a needle guide (12) which can be operated
5 from the outside and used for collecting tissue samples from the human body, the needle guide (12) being separate from the other part of the apparatus which for hygienic reasons is covered by a sterile sheath (14), characterised in that the needle guide (12) is retained by being pressed into a recess in the other part of the apparatus after the sterile sheath (14) has been arranged on the apparatus.
- 10 2. Apparatus according to claim 1, characterised in that the needle guide (12) is retained by means of a needle guide holder (16) which can be clipped firmly onto the other part of the apparatus after the sheath (14) has been arranged on the apparatus.
3. Apparatus according to claim 3, characterised in that the needle guide holder (16) is formed as a sector of circle in cross-section.
- 15 4. Apparatus according to claims 3 or 4, characterised in that the needle guide and the needle guide holder are formed integrally.

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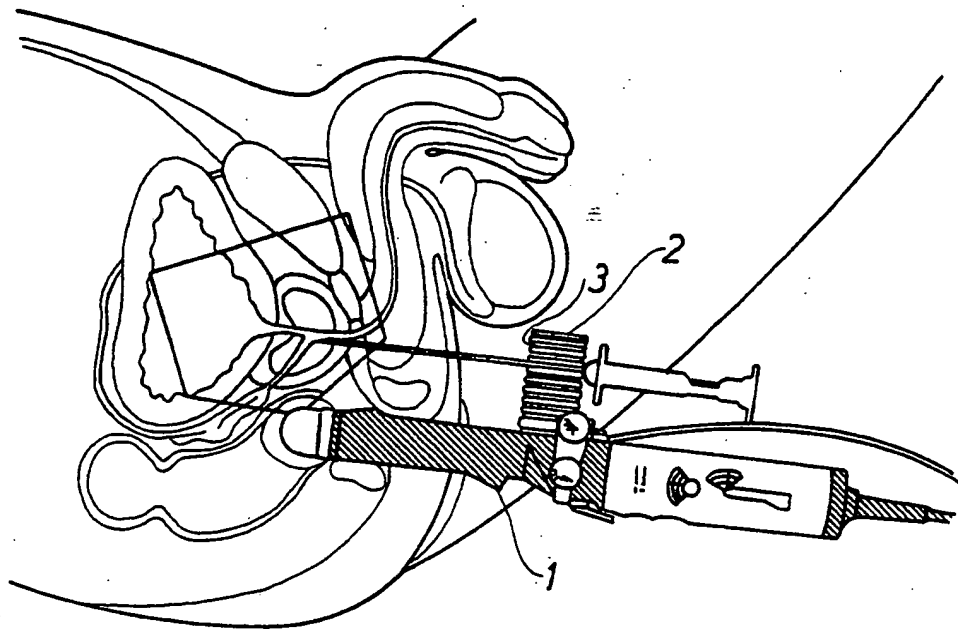


Fig. 1

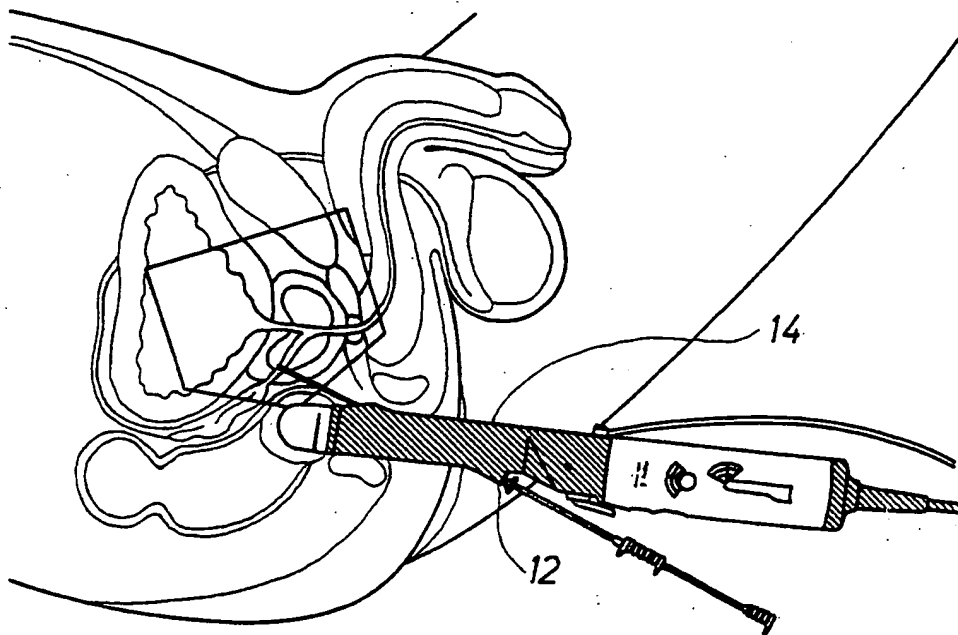


Fig. 2

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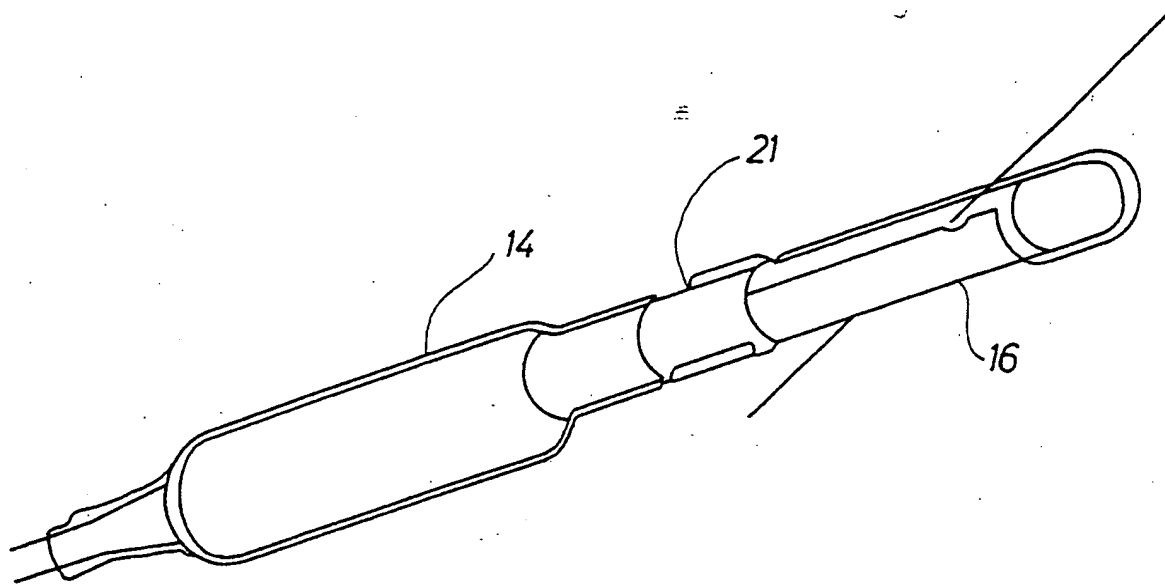


Fig. 3

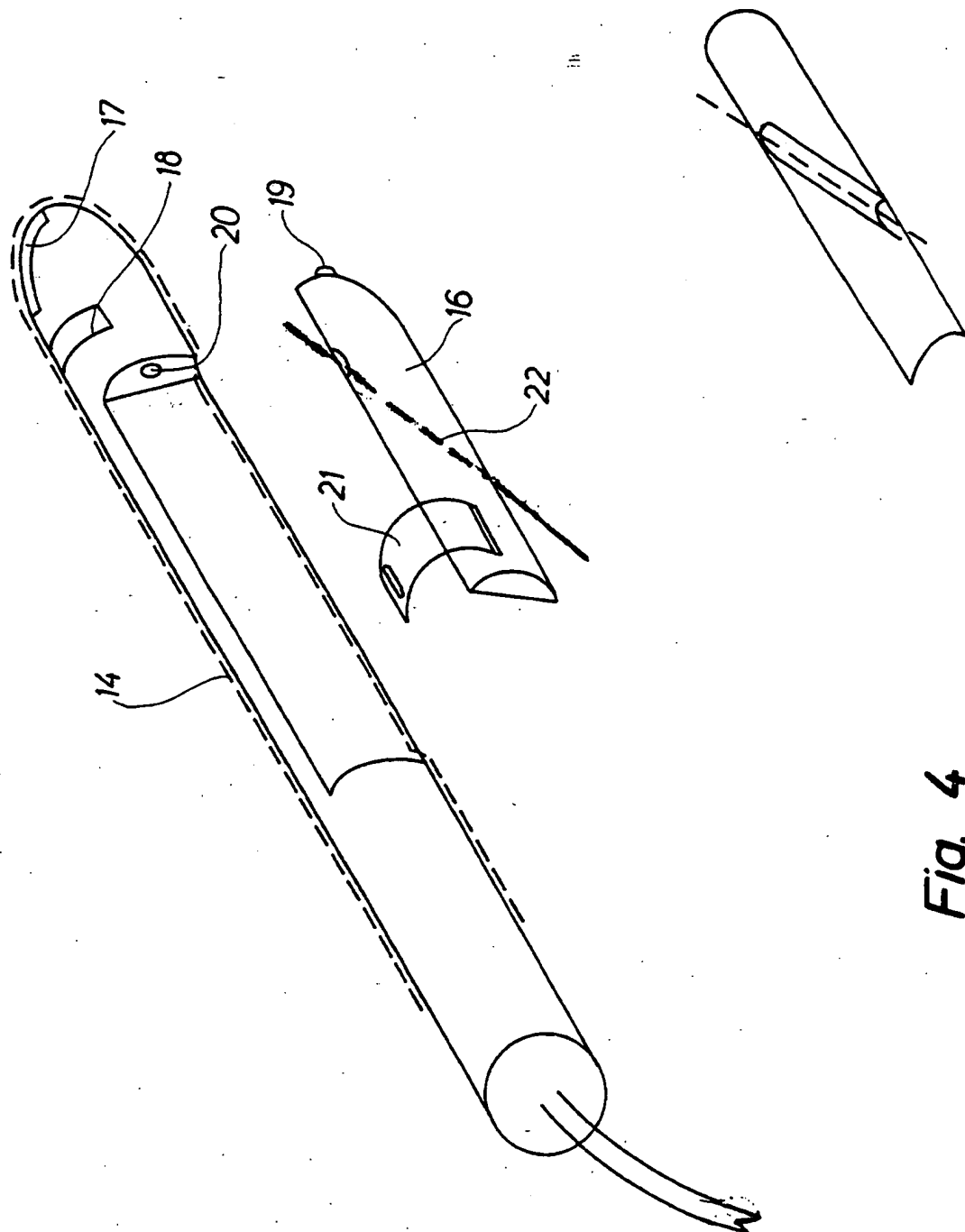


Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 99/00001

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 10/00, A61B 8/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5235987 A (J.K. WOLFE), 17 August 1993 (17.08.93), column 2, line 4 - line 41, figure 1 --	1-5
X	US 4742829 A (W. LAW ET AL.), 10 May 1988 (10.05.88), column 1, line 55 - column 2, line 27, figure 3 --	1-5
A	US 5090414 A (M. TAKANO), 25 February 1992 (25.02.92), figure 8, abstract -- -----	1-5

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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INTERNATIONAL SEARCH REPORT

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Patent document cited in search report			Publication date	Patent family member(s)	Publication date
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